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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,273

02/07/2006

Lynne E Maquat

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

11/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,273	Applicant(s) MAQUAT, LYNN E	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 15-36 and 38-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Seq Compliance Notice</u> |

DETAILED ACTION

This Office action is in response to the communication filed 9-12-08.

Claims 1-73 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group IV, claim 37 in the reply filed on 9-12-08 is acknowledged. The traversal is on the ground(s) that all of the Groups related to the special technical feature of substances that modulate NMD and their uses.

Applicant also argues that the Examiner has not provided any evidence that disclosures exist in the prior art that would destroy novelty or inventive of the common technical feature. This is not found persuasive because the different Groups are directed to distinct methods (e.g. methods of treating a disorder, methods of screening for substance that modulate, methods modulating NMD activity, methods of making substances capable of modulating NMD...), and each of these methods involves distinct steps, and/or measure different biological or biochemical outcomes. Furthermore, the methods further involve the use of a myriad of possible combinations or subcombinations of components. In the instant case, the particular combination as claimed does not require the particulars of the subcombination as claimed, because the presence of the claims to the combination of various and distinct subcomponents of the substances, ranging from two through fourteen components, and listed in various subcombinations in the claims, is evidence that the details of the first subcombination are not required for patentability, and vice versa.

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The requirement is still deemed proper and is therefore made FINAL.

Applicant additionally argues that claim 14 should also be examined because both claims 14 and 37 are directed to methods of screening for substances that modulate NMD.

Claims 1-13, 15-36, 38-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9-12-08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of screening for modulators of nonsense-mediated mRNA decay (NMD) comprising incubating a substance with an NMD complex or with a

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system, and assaying for a change (increase or decrease) in NMD in the presence and absence of the candidate modulator.

The specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of the genera comprising either an *NMD complex* or a *system*. The specification and the prior art teach a myriad of candidate molecules that are involved in, and potentially participate in the modulation of NMD, including, but not limited to UPF1, UPF2, UPF3, UPF3X, SMG1, ATX, ERF1, ERF3, REF, ALY, Y14, DEK, SRm160, RNPS1, TAP, CBP80, EIF4E, PP2A, CeSMG5, CeSMG7, CeSMG7a, Dcp2, PM, Scl100, and PARN, as well as SRm160, to name a few (see, e.g., Hir et al, EMBO J., Vol. 20, No. 17, pages 4987-4997, 2001). The effects of post-translational modifications of these molecules, and the cascades involved in those modifications, and how such modifications affect NMD, are currently under investigation in many laboratories around the world. It is therefore difficult to adequately describe the members of the broad genera claimed, encompassing *NMD complexes* or *systems* that are assayed for changes in NMD in the presence of a candidate modulator, because the potential genera are expansive.

Concise structural features that could distinguish structures within each genus from others are missing from the disclosure. No common structural attributes, or concise entity of participating molecules identify the members of the broadly claimed genera, and distinguish members within each claimed genus from those outside of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to

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provide a concise description of the genera claimed. Thus, Applicant was not in possession of the broadly claimed genera.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 14 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al (WO 99/20797).

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He et al (WO 99/20797) teach methods of screening for a substance that modulates NMD comprising administering a substance to a system or to an NMD complex, and assaying the effect of the substance on the amount of NMD activity (see the abstract; pages 3-5; 13; 15; 17; 21-22; 26-27; 34-35; 36-37; 42; 51; 56; 58; 65-66; 73; claims 1-11).

Claims 14 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckmann et al (US 2006/0134681).

Beckmann et al (US 2006/0134681) teach methods of screening for a substance that modulates NMD comprising administering a substance to a system or to an NMD complex, and assaying the effect of the substance on the amount of NMD activity (see the abstract; pages 1-2, esp. paragraphs 0007-0010, 0025; page 3, esp. paragraph 0035; page 7, paragraph 0087-8; page 8 in its entirety; claims 1-4, 16, 35-37).

Claims 14 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Peltz et al (USPN 6,486,305).

Peltz et al (USPN 6,486,305) teach methods of screening for a substance that modulates NMD comprising administering a substance to a system or to an NMD complex, and assaying the effect of the substance on the amount of NMD activity (see esp. the abstract; col. 1-4; col. 11, 13-15; 19-21, 41-43).

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Please provide SEQ ID NOs. for the sequences listed in claims 32, 33; figures 15, 20, and where appropriate in the specification.** Please see the accompanying *Notice to Comply*.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of

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a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
11-12-08

/Jane Zara/

Primary Examiner, Art Unit 1635